Citation:

St-Onge MP, Aban I, Bosarge A, Gower B, Hecker KD, Allison DB. Snack chips fried in corn oil alleviate cardiovascular disease risk factors when substituted for low-fat or high-fat snacks. *Am J Clin Nutr.* 2007 Jun;85(6):1503-10.

PubMed ID: 17556685

Study Design:

Randomized Crossover Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The objective of this study was to determine whether replacing low-fat and high-fat or high-saturated fat and high-*trans* fat snack foods with snacks high in fat (mostly PUFAs) and low in saturated and *trans* fats improves cardiovascular disease (CVD) risk factors.

Inclusion Criteria:

- Fasting LDL-cholesterol concentrations of 130-180 mg/dL
- Triacylglycerol concentrations <350 mg/dL
- Glucose concentrations <126 mg/dL
- BMI 20-35
- Stable weight for ≥3 months before the study
- Informed consent

Exclusion Criteria:

- Use of lipid-lowering medication (if taking other medications, they were required to continue the medication at the same dosage throughout the entire study)
- History of CVD
- Current smoking
- Type 1 or 2 diabetes
- Hypertension

Description of Study Protocol:

Recruitment :

Recruitment methods were not described. The initial screening process occurred via telephone

questionnaire.

Design: Randomized crossover trial with 3 controlled feeding phases over a period of 7 months.

Blinding used (if applicable): No blinding was reported.

Intervention (if applicable):

- There were 3 diet phases of 25 days each, which were separated by either an 8- or a 4-week washout period.
- During washout periods, subjects resumed normal eating habits.
- Subjects were randomly assigned to start with the same base diet to which was added one of three types of snacks: low fat (LF), high fat (HF), or high PUFA (HPUFA).
- Snacks provided 12-15% of energy (about 300 kcals/day) and consisted of fat free cookies, crackers and cereal bars for the LF diet, chocolate bars, high fat cookies and crackers, and buttered popcorn for the HF diet, and corn and tortilla snack chips fried in corn oil for the HPUFA diet.
- The low fat diet provided total fat and saturated fat at 30% and <10% energy respectively, with 5.2% from PUFAs.
- The high fat diet provided 37.9% energy from fat, 5.8% from PUFAs
- The high PUFA diet provided 36.3% energy from fat with low saturated fat (8.5%), more PUFA (9.7%) and low *trans* fat (0.7%).
- Food was prepared for the subjects and breakfast was eaten under supervision. Weight was measured and subjects were required to maintain a stable body weight.
- If body weight varied by >1%, caloric adjustment was made in the foods provided.

Statistical Analysis:

- For all continuous response variables, generalized linear models for repeated measures in SAS PROC MIXED were used to investigate the effect of diet on the percentage of change from baseline values.
- Correlations of repeated measures were estimated.
- Generalized estimating equations method was applied to a logistic model to investigate the effect of diet on the odds that a person would have atherogenic LDL pattern B.
- Covariates included in the model were baseline values, phase (order in which diet was given), day after starting diet, age, and sex.
- A 2-tailed 5% significance level was used.

Data Collection Summary:

Timing of Measurements: Measures were taken at baseline and on days 15 and 25 of each diet phase.

Dependent Variables: The following samples/measures were collected following standard anthropometric and laboratory procedures:

- Weight, hip and waist circumferences, and body fat (BIA)
- Blood pressure
- Lipoprotein profile (total, HDL, LDL and VLDL cholesterol) and triacylglycerides

Independent Variables:

- The base diet

- Three types of snacks which comprised the LF, HF and HPUFA diets

Control Variables:

- Subjects were asked to maintain the same amount of exercise during the course of the study and they kept exercise records for documentation.
- Baseline values
- Phase (order in which diet was given)
- Day after starting diet
- Age
- Sex

Description of Actual Data Sample:

Initial N: 45 volunteer subjects were enrolled.

Attrition (final N): 33 (7 male, 26 female) completed all phases of the study. Subjects discontinued due to straying from the diet (n = 2), food complaints (n = 5), did not return (n = 2), pregnant (n = 1), work conflict (n = 1), and death in family (n = 1).

Age: 41.8 ± 1.9 years

Ethnicity: not described

Other relevant demographics:

Anthropometrics BMI 29 ± 0.6

Location: Clinical Research Center, Birmingham, AL

Summary of Results:

Key Findings

- There was a significant effect of diet on LDL cholesterol, total cholesterol and triacylglycerol
- All three diets reduced LDL cholesterol and total cholesterol concentrations, and low fat and high PUFA did so to a greater extent than the high fat diet: LDL cholesterol decreased by 11.8% and 12.5% compared with 8.8% (P = 0.03 and 0.01), respectively, and total cholesterol decreased by 10.5% and 10.7% compared with 7.9% (P = 0.03 and P = 0.02), respectively.
- The HPUFA diet tended to reduce triacylglycerol concentrations (9.4%, P = 0.06) more than the other diets: low-fat (P = 0.028) and high-fat (P = 0.008)
- There was no significant effect of diet on change in waist circumference, percentage body fat, or blood pressure.

Percentage Changes in Serum Lipid Concentrations (Mean ± SEM)

Lipid	LF Diet	High PUFA Diet	High Fat Diet	P
LDL-C	-11.8 ±1.9	-12,5±1.9	-8.8±1.9	0.0004
TC	-10.5±1.4	-10.7±1.4	-7.9±1.4	0.0014

HDL-C	-11.1±2.1	-8.2±2.2	-10.2±2.1	0.0015
TG	6±4.8	-9.4±4.8	0.2±4.8	<0.0001
VLDL-C	4±2.8	-5±2.8	1.8±2.8	<0.0001

Author Conclusion:

These data show that snack type affects cardiovascular health. Consuming snack chips rich in PUFA and low in saturated or *trans* fatty acids instead of high-saturated fatty acid and *trans* fatty acid or low-fat snacks leads to improvements in lipid profiles concordant with reductions in cardiovascular disease risk.

Reviewer Comments:

small sample size limits power and generalizability of the findings. Subjects were mildly hyperlipidemic and normoglycemic. Subjects may not have been entirely compliant with the diet. The feeding periods of 25 days may not have been long enough to initiate a change in some endpoints. Sponsored by Frito Lay.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes

1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	???
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	N/A
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A

5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	???
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	???
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes

	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		???
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	???